''(2) could be used in a public health emergency.

''(d) DEFINITION.—In this section, the terms 'Advisory Committee on Immunization Practices' and 'Advisory Committee' mean the Advisory Committee on Immunization Practices established by the Secretary pursuant to section 222 of the Public Health Service Act (42 U.S.C. 217a), acting through the Director of the Centers for Disease Control and Prevention.''

§ 360bbb–4a. Priority review to encourage treatments for agents that present national security threats

(a) Definitions

In this section:

(1) Human drug application

The term ''human drug application'' has the meaning given such term in section 379g(1) of this title.

(2) Priority review

The term ''priority review'', with respect to a human drug application, means review and action by the Secretary on such application not later than 6 months after receipt by the Secretary of such application, as described in the Manual of Policies and Procedures in the Food and Drug Administration and goals identified in the letters described in section 101(b) of the Food and Drug Administration Safety and Innovation Act.

(3) Priority review voucher

The term ''priority review voucher'' means a voucher issued by the Secretary to the sponsor of a material threat medical countermeasure application that entitles the holder of such voucher to priority review of a single human drug application submitted under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] after the date of approval of the material threat medical countermeasure application.

(4) Material threat medical countermeasure application

The term ''material threat medical countermeasure application'' means an application that—

(A) is a human drug application for a drug intended for use—

(i) to prevent, or treat harm from a biological, chemical, radiological, or nuclear agent identified as a material threat under section 319F–2(c)(2)(A)(ii) of the Public Health Service Act [42 U.S.C. 247d–6b(c)(2)(A)(ii)]; or

(ii) to mitigate, prevent, or treat harm from a condition that may result in adverse health consequences or death and may be caused by administering a drug, or biological product against such agent; and

(B) the Secretary determines eligible for priority review;

(C) is approved after December 13, 2016; and

(D) is for a human drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)].

(b) Priority review voucher

(1) In general

The Secretary shall award a priority review voucher to the sponsor of a material threat medical countermeasure application upon approval by the Secretary of such material threat medical countermeasure application.

(2) Transferability

The sponsor of a material threat medical countermeasure application that receives a priority review voucher under this section may transfer (including by sale) the entitlement to such voucher to a sponsor of a human drug for which an application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] will be submitted after the date of the approval of the material threat medical countermeasure application. There is no limit on the number of times a priority review voucher may be transferred before such voucher is used.

(3) Notification

(A) In general

The sponsor of a human drug application shall notify the Secretary not later than 90 calendar days prior to submission of the human drug application that is the subject of a priority review voucher of an intent to submit the human drug application, including the date on which the sponsor intends to submit the application. Such notification shall be a legally binding commitment to pay for the user fee to be assessed in accordance with this section.

(B) Transfer after notice

The sponsor of a human drug application that provides notification of the intent of such sponsor to use the voucher for the human drug application under subparagraph (A) may transfer the voucher after such notification is provided, if such sponsor has not yet submitted the human drug application described in the notification.

(c) Priority review user fee

(1) In general

The Secretary shall establish a user fee program under which a sponsor of a human drug application that is the subject of a priority review voucher shall pay to the Secretary a fee determined under paragraph (2). Such fee shall be in addition to any fee required to be submitted by the sponsor under subchapter VII.

(2) Fee amount

The amount of the priority review user fee shall be determined each fiscal year by the Secretary and based on the average cost incurred by the agency in the review of a human drug application subject to priority review in the previous fiscal year.

(3) Annual fee setting

The Secretary shall establish, before the beginning of each fiscal year beginning after September 30, 2016, for that fiscal year, the amount of the priority review user fee.

(4) Payment

(A) In general

The priority review user fee required by this subsection shall be due upon the submission of a human drug application under section 355(b)(1) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for which the priority review voucher is used.

(B) Complete application

An application described under subparagraph (A) for which the sponsor requests the use of a priority review voucher shall be considered incomplete if the fee required by this subsection and all other applicable user fees are not paid in accordance with the Secretary's procedures for paying such fees.

(C) No waivers, exemptions, reductions, or refunds

The Secretary may not grant a waiver, exemption, reduction, or refund of any fees due and payable under this section.

(5) Offsetting collections

Fees collected pursuant to this subsection for any fiscal year—

(A)[1] shall be deposited and credited as offsetting collections to the account providing appropriations to the Food and Drug Administration; and

(6)[2] shall not be collected for any fiscal year except to the extent provided in advance in appropriation Acts.

(d) Notice of issuance of voucher and approval of products under voucher

The Secretary shall publish a notice in the Federal Register and on the Internet website of the Food and Drug Administration not later than 30 calendar days after the occurrence of each of the following:

(1) The Secretary issues a priority review voucher under this section.

(2) The Secretary approves a drug pursuant to an application submitted under section 355(b) of this title or section 351(a) of the Public Health Service Act [42 U.S.C. 262(a)] for which the sponsor of the application used a priority review voucher issued under this section.

(e) Eligibility for other programs

Nothing in this section precludes a sponsor who seeks a priority review voucher under this section from participating in any other incentive program, including under this chapter, except that no sponsor of a material threat medical countermeasure application may receive more than one priority review voucher issued under any section of this chapter with respect to such drug.

(f) Relation to other provisions

The provisions of this section shall supplement, not supplant, any other provisions of this chapter or the Public Health Service Act [42 U.S.C. 201 et seq.] that encourage the development of medical countermeasures.

(g) Sunset

The Secretary may not award any priority review vouchers under subsection (b) after October 1, 2023.

(June 25, 1938, ch. 675, § 565A, as added Pub. L. 114–255, div. A, title III, § 3086, Dec. 13, 2016, 130 Stat. 1144.)

Editorial Notes

REFERENCES IN TEXT

Section 101(b) of the Food and Drug Administration Safety and Innovation Act, referred to in subsec. (a)(2), is section 101(b) of Pub. L. 112–144, which is set out as a note under section 379g of this title.

The Public Health Service Act, referred to in subsec. (f), is act July 1, 1944, ch. 373, 58 Stat. 682, which is classified generally to chapter 6A (§ 201 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 201 of Title 42 and Tables.

§ 360bbb–4b. Medical countermeasure master files

(a) Applicability of reference

(1) In general

A person may submit data and information in a master file to the Secretary with the intent to reference, or to authorize, in writing, another person to reference, such data or information to support a medical countermeasure submission (including a supplement or amendment to any such submission), without requiring the master file holder to disclose the data and information to any such persons authorized to reference the master file. Such data and information shall be available for reference by the master file holder or by a person authorized by the master file holder, in accordance with applicable privacy and confidentiality protocols and regulations.

(2) Reference of certain master files

In the case that data or information within a medical countermeasure master file is used only to support the conditional approval of an application filed under section 360ccc of this title, such master file may be relied upon to support the effectiveness of a product that is the subject of a subsequent medical countermeasure submission only if such application is supplemented by additional data or information to support review and approval in a manner consistent with the standards applicable to such review and approval for such countermeasure, qualified countermeasure, or qualified pandemic or epidemic product.

(b) Medical countermeasure master file content

(1) In general

A master file under this section may include data or information to support—

(A) the development of medical countermeasure submissions to support the approval, licensure, classification, clearance, conditional approval, or authorization of one or more security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products; and

(B) the manufacture of security countermeasures, qualified countermeasures, or qualified pandemic or epidemic products.

[1] So in original. No subpar. (B) has been enacted.

[2] So in original. Probably should be designated as subpar. (B).